



Europäisches Patentamt  
European Patent Office  
Office européen des brevets



Publication number:

**0 636 345 A1**

(12)

## EUROPEAN PATENT APPLICATION

(21) Application number: **94111165.0**

(51) Int. Cl.<sup>8</sup>: **A61B 17/32**

(22) Date of filing: **18.07.94**

(30) Priority: **26.07.93 US 96297**

(43) Date of publication of application:  
**01.02.95 Bulletin 95/05**

(84) Designated Contracting States:  
**DE ES FR GB IT**

(71) Applicant: **SENTINEL MEDICAL, INC.**  
**1895-A Beaver Run Road**  
**Norcross,**  
**Georgia 30071 (US)**

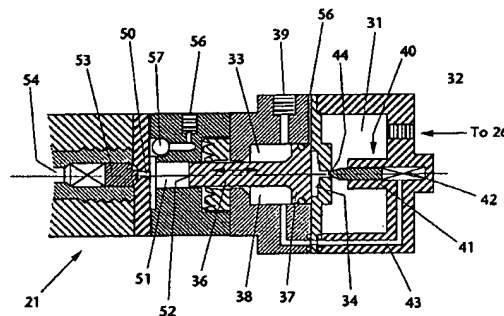
(72) Inventor: **Bair, Scott**  
**1603 Trentwood Place**  
**Atlanta,**  
**Georgia 30319 (US)**

(74) Representative: **Marsh, Roy David et al**  
**Hoffmann Eitle & Partner**  
**Patent- und Rechtsanwälte**  
**Arabellastrasse 4**  
**D-81925 München (DE)**

(54) **Fluid jet surgical cutting tool.**

(57) A pulsed fluid jet surgical instrument includes a cannula 22 extending from a handpiece 21, the cannula emitting a pulsed fluid jet for cutting and emulsification purposes, and also providing suction for aspiration and evacuation of the fluid and tissue. A pressure intensifier piston arrangement 36 receives fluid at relatively low pressure, and operates reciprocally and reiteratively to pump the fluid through the jet needle 54 in a series of high pressure pulses, each having a nearly rectangular pressure waveform. The pressure intensifier piston is T-shaped, including a broad end 37 which divides a drive bore into a driving chamber and a retracting chamber. A bistable valve 40 is connected to admit high pressure gas into the actuating chamber, driving the piston to translate. The narrow end of the piston is disposed in a fluid pumping chamber connected to a supply of fluid. The translating piston drives the fluid from the pumping chamber through a first check valve into a fluid jet needle, which directs the high pressure fluid pulse to a tissue target. The bistable valve switches to admit pressurized gas to the retracting chamber, driving the piston retrograde and allowing the pumping chamber to refill with fluid through a second check valve. There is no high

pressure fluid supplied to the handpiece, and only the pressure intensifying pumping action of the piston creates a high pressure fluid pulse. The gas supply to drive the piston is at a relatively low pressure, so that gas pressure cannot comprise a safety risk to the patient. Thus failure of the piston mechanism cannot result in the emission of a stream of high pressure fluid, and the instrument is inherently safer than prior art instruments that are connected to a high pressure fluid source.



Figure\_3

EP 0 636 345 A1

### Background of the Invention

The present invention generally relates to surgical cutting tools, and more particularly to cutting tools employing a fluid jet as the active cutting agent.

There is currently a great amount of interest in new technologies to replace or supplant traditional surgical cutting tools such as the scalpel. Laser-based tools, electrosurgical cutters, plasma jets, and fluid jets have all been introduced to improve various surgical and medical procedures. Each technology has advantages for particular procedures, as well as intrinsic drawbacks. Fluid jet cutters have several characteristics that make it all attractive new technology. For example, pulsed fluid jet cutters involve no electrical current or voltage, which can comprise a safety risk factor in delicate surgeries. Likewise, there is little heat generated by fluid jets. Indeed, fluid jets are inherently self-cooling. Also, the effects of pulsed fluid jets can be extremely localized and directional, unlike electrosurgical tools and some laser instruments.

Moreover, fluid jet cutters excel at removing soft tissue, due to the fact that high pressure pulsed jets tend to emulsify soft tissue, and the emulsified tissue is easily transported by aspiration away from the surgical site. In contrast, competing technologies such as laser cutters and electrosurgical cutters remove tissue by ablation or electrothermal dissolution. Both of these effects tend to create collateral thermal damage and necrosis, which is generally unwanted and often intolerable for medical purposes.

Indeed, the fact that fluid jet cutting devices include aspiration and evacuation as an integral portion of the device is an added benefit for many surgical procedures. Surgical cutting and excision often involves exsanguination that occludes the surgical field, and the surgeon must employ an assistant to aspirate the field to permit adequate visualization. Fluid jet devices that aspirate the fluid and emulsified tissue also remove the blood and other fluids that might otherwise affect visualization by the surgeon, and they do so without involving additional personnel.

However, fluid jet devices known in the prior art do exhibit some negative characteristics that limit their usefulness. Within restricted body cavities and organs, the volume of fluid introduced by the cutting instrument may exceed the aspiration ability of the instrument, resulting in distention and expansion that can have deleterious side effects. The emulsification effect is primarily a consequence of pulsing the high pressure fluid jet, and the pulse parameters are critical in efficiently emulsifying tissue. Generally speaking, prior art fluid jet tools have not been capable of achieving sufficiently

short, well-defined pulses of high pressure fluid to emulsify tissue effectively and completely. Any portion of a fluid pulse that is not delivered at high pressure is ineffective, and merely adds fluid to the surgical field. As a result, a greater volume of fluid is consumed for a given cutting or excision procedure, requiring more time for the surgeon and the provision of more robust aspiration capabilities in the tool.

As a safety measure, it is critical that any fluid jet cutting tool be prevented from emitting a steady stream of high pressure fluid, which can quickly penetrate deeply into soft tissue and can cause catastrophic damage. Some prior art pulsed fluid jet instruments are not designed to inherently prevent a high pressure stream, and must be carefully controlled by external devices to avoid serious accidents.

### Summary of the Invention

The present invention generally comprises a pulsed fluid jet instrument for surgical cutting and excision. A salient feature of the instrument is that it is designed to be inherently safe by preventing the emission of a steady stream of high pressure fluid into tissue. Moreover, the instrument has superior pulse characteristics which optimize cutting and emulsification while minimizing the amount of fluid used in the process.

The instrument of the invention includes a cannula extending from a handpiece, the cannula having an inner needle designed to emit a pulsed fluid jet for cutting and emulsification purposes, and at outer concentric needle or tube connected to a negative pressure source for aspiration and evacuation of the fluid and tissue. The handpiece features a pressure intensifier piston arrangement that receives fluid at relatively low pressure, and operates reciprocally and reiteratively to pump the fluid through the jet needle in a series of high pressure pulses, each having a nearly rectangular pressure waveform.

The pressure intensifier piston is T-shaped, including a broad end which divides a drive bore into an actuating chamber and a retracting chamber. A bistable valve is connected to admit high pressure gas into the actuating chamber, driving the piston to translate. The narrow end of the piston is disposed in a fluid pumping chamber that is connected to a supply of fluid. The translating piston drives the fluid from the pumping chamber through a first check valve into the fluid jet needle, which directs the high pressure fluid pulse to a tissue target. The bistable valve switches to admit pressurized gas to the retracting chamber, driving the piston retrograde and allowing the pumping chamber to refill with fluid through a second check

valve.

There is no high pressure fluid supplied to the handpiece, and only the pressure intensifying pumping action of the piston creates a high pressure fluid pulse. Moreover, the gas supply to drive the piston is at a relatively low pressure, so that gas pressure cannot comprise a safety risk to the patient. Thus failure of the piston mechanism cannot result in the emission of a stream of high pressure fluid, and the instrument is inherently safer than prior art instruments that are connected to a high pressure fluid source.

#### Brief Description of the Drawing

Figure 1 is a functional block diagram of the fluid jet surgical instrument of the present invention.

Figure 2 is a perspective view showing the fluid jet surgical instrument in use.

Figure 3 is a cross-sectional view of the pressure intensifier portion of the fluid jet surgical instrument of the present invention.

Figure 4 is a cross-sectional view of another embodiment of the pressure intensifier portion of the fluid jet surgical instrument.

Figure 5 is a cross-sectional view of the cannula portion of the fluid jet surgical instrument.

Figure 6 is an end view of the cannula portion of the fluid jet surgical instrument.

#### Description of the Preferred Embodiment

The present invention generally comprises a pulsed fluid jet surgical instrument for cutting, excision, and emulsification and removal of tissue. With reference to Figure 1, the instrument includes a handpiece 21 adapted to be wielded manually, with a cannula 22 extending therefrom. The cannula emits a pulsed jet of high pressure fluid for surgical cutting and tissue emulsification. The cannula 22 is connected to an aspiration system 23 which provides vacuum aspiration to remove the fluid introduced by the instrument, as well as body fluids and emulsified tissue. The handpiece 21 is also connected to a low pressure fluid supply 24 that provides the fluid which forms the high pressure pulsed cutting jet. A low pressure gas supply 26 is also connected to the handpiece 21 to power the handpiece to produce high pressure fluid pulses.

The instrument is wielded by a surgeon as shown in Figure 2 to produce surgical cutting and excision effects for therapeutic purposes. It should be noted initially that the handpiece 21 is devoid of any connection to a high pressure source of any kind, so that no failure mode of the invention can introduce a high pressure fluid stream into the

patient. Thus the invention is inherently safer than many similar instruments known in the prior art.

With regard to Figure 3, the handpiece 21 includes an interior gas reservoir 31 that is connected through port 32 to the low pressure gas supply 26. The handpiece also provides a piston 36 having a broad head 37 that is disposed concentrically in a bore 33 in a pressure sealing, translating fashion. The head 37 divides the bore 33 into a driving chamber 34 and a retracting chamber 38. The retracting chamber communicates through port 39 to an actuating valve (not shown) that selectively vents the retracting chamber 38 and permits pulsed operation of the unit. The actuating valve may comprise a pneumatic switch on the handpiece, or a footswitch coupled by tubing to the port 39.

The handpiece further includes a bistable valve assembly 40, comprised of a valve pintle 41 slidably disposed in a bore 42. The bore 42 is connected through passageway 43 to the retracting chamber 38 of the bore 33. A valve port 44 extends from the driving chamber 34 to the gas reservoir 31, and the tip of the valve pintle 41 seats in the port 44 to selectively block gas flow from the reservoir to the driving chamber. A compression spring is disposed in the bore 42 to bias the pintle to close the port 44.

The piston 36 includes a narrow pumping end 52 disposed in a pump chamber 51. The pump chamber 51 communicates through an outlet passage 50 to a relief valve 53, which in turn leads to a tube 54 connected to the jet outlet port. The relief valve is set to open at a relatively high pressure, so that no fluid flow is admitted to the jet outlet port until pressure in the pump chamber attains a high value. With this arrangement, the jet pulses are comprised solely of high pressure fluid, and the pressure versus time profile of each pulse approaches a rectangular waveform. Fluid such as sterile saline solution, Ringer's solution, or the like is supplied to the pump chamber from supply 24 through inlet port 56 and ball check valve 57.

To operate the apparatus depicted in Figure 3, the actuating valve connected to port 39 is opened, venting the retracting chamber to ambient pressure. The pressure in bore 42 likewise drops, due to the flow communication of passageway 43, and the gas pressure in reservoir 31 overcomes the spring force acting on the pintle 41. The pintle 41 is driven into the bore 42, opening the port 44 and admitting pressurized gas from the reservoir 31 into the driving chamber 34. The piston translates toward the jet tube 54, compressing the fluid in the pump chamber 51. When the pressure in the fluid chamber exceeds the threshold of the relief valve 53, fluid is expelled through the jet tube 54 as a high pressure fluid pulse.

It is significant to note that driving surface of the piston head 37 is far greater in area than the pump end 52, and that the force developed at the head 37 is transmitted to a far smaller fluid surface area in the pump chamber. As a result, the gas pressure driving the piston is greatly amplified (on the order of ten times or more), thereby creating a very high pressure pulse from a low pressure fluid supply and a low pressure gas supply. For example, fluid may be provided at approximately 100 psig, and the relief valve may be set to open at 300 psid or more. The maximum pressure developed during the pressure pulse may exceed 1000 psig, even though the gas pressure supplied to the instrument may be 100-120 psig.

When the actuating valve is closed, gas pressure leaking past the pintle 41 and through the passageway 43 begins to build pressure in the retracting chamber 38. Pressure also builds in the bore 42, urging the pintle to translate and seal the inlet port 44. Gas pressure bleeds from the driving chamber 34 through a bleed passage 56, and the piston retracts. The relief valve 53 closes when the piston begins to retract, and inlet valve 57 opens to permit the pump chamber to refill. Thus one high pressure fluid jet pulse is completed, and the apparatus is set to deliver another pulse. However, it should be noted that the actuating valve must be reopened to initiate another pulse, and that the mechanism is not free-running. Thus there is no possibility of the instrument delivering additional pulses after shutdown is desired, and the apparatus is inherently safe in another important characteristic.

With regard to Figure 4, a further embodiment 121 of the handpiece is designed to optimize the mechanical design of the instrument for efficient manufacturing, cleaning, and servicing. The handpiece 121 includes an interior gas reservoir 131 that is connected through side port 132 to the low pressure gas supply 26. The handpiece includes a piston 136 having a broad head 137 that is disposed concentrically in a bore 133 in a pressure sealing, translating fashion. The head 137 divides the bore 133 into a driving chamber 134 and a retracting chamber 138. The retracting chamber communicates through port 139 to an actuating valve (not shown) that selectively vents the retracting chamber 138 to permit pulsed operation of the unit. The actuating valve may comprise a pneumatic switch on the handpiece, or a footswitch coupled by tubing to the port 139. A bleed port 156 extends from the driving chamber 134 to ambient atmosphere.

The handpiece further includes a bistable valve assembly 140, comprised of a valve pintle 141 slidably disposed in a bore 142. A valve port 144 extends from the driving chamber 134 through port

161 to the gas reservoir 131, and the tip of the valve pintle 141 seats in the port 144 to selectively block gas flow from the reservoir to the driving chamber. A compression spring 145 is disposed in the bore 42 to bias the pintle to close the port 144. A connector 160 is coupled to the outer end of the bore 142, and is connected to join the bore 142 in flow communication with the port 139 of the retracting chamber 138.

The piston 136 includes a narrow pumping end 152 disposed in a pump chamber 151. The pump chamber 151 communicates through an outlet passage 150 to a relief valve 153, which in turn leads to a tube 154 connected to the jet outlet port. The relief valve is set to open at a relatively high pressure, so that no fluid flow is admitted to the jet outlet port until pressure in the pump chamber attains a high value. With this arrangement, the jet pulses are comprised solely of high pressure fluid, and the pressure versus time profile of each pulse approaches a rectangular waveform. Fluid such as sterile saline solution, Ringer's solution, or the like is supplied to the pump chamber from supply 24 through inlet port 156 and check valve 157.

To operate the apparatus 121, the actuating valve connected to port 139 and 160 is opened, venting the retracting chamber to ambient pressure. The pressure in bore 142 likewise drops, due to the flow connection between port 139 and connector 160, and the gas pressure delivered through port 161 from reservoir 131 overcomes the spring force acting on the pintle 141. The pintle 141 is driven into the bore 142, opening the port 144 and admitting pressurized gas from the reservoir 131 into the driving chamber 134. The piston translates toward the jet tube 154, compressing the fluid in the pump chamber 151. When the pressure in the fluid chamber exceeds the threshold of the relief valve 153, fluid is expelled through the jet tube 154 as a high pressure fluid pulse.

When the actuating valve is closed, gas pressure leaking past the pintle 141 and through the connection to port 139 begins to build pressure in the retracting chamber 138. Pressure also builds in the bore 142, allowing the spring 145 to urge the pintle to translate and seal the inlet port 144. Gas pressure bleeds from the driving chamber 134 through the bleed passage 156, and the higher pressure in the retracting chamber causes the piston 136 to retract. The relief valve 153 closes when the piston begins to retract, and inlet valve 157 opens to permit the pump chamber to refill. Thus one high pressure fluid jet pulse is completed, and the apparatus is set to deliver another pulse. As in the previous embodiment, the actuating valve must be reopened to initiate another pulse, and the mechanism is not free-running. Thus there is no possibility of the apparatus delivering additional

pulses after shutoff is desired.

With regard to Figures 5 and 6, the cannula assembly 22 of the invention includes an aspiration tube 201 extending coaxially and distally from a housing 202. A jet tube 203 is disposed concentrically and coaxially within the aspiration tube 201, and is supported by a mandrel 204 secured within the housing 202. The distal end of the jet tube is recessed slightly within the distal end of the aspiration tube, and the proximal end of the jet tube is connected to the high pressure pulse output 54 or 154 described previously. The interior of the housing 202 communicates with the interior space of the aspiration tube 201, and port 206 connects the aspiration tube to the aspiration system 23 described previously. The housing 202 is joined to the either of the handpieces 21 or 121 described above.

The distal end of the jet tube 203 emits a train of pulses of high pressure fluid from the handpiece apparatus, causing the target tissue to be cut and emulsified. The suction provided by the aspiration tube removes the fluid emitted by the jet tube, as well as the emulsified tissue and body fluids, so that surgical cutting and tissue excision and removal may be carried out quickly and efficiently.

The claims which follow identify embodiments of the invention additional to those described in detail above.

#### Claims

1. A fluid jet surgical cutting instrument, comprising:
  - a housing having a fluid inlet;
  - a cannula extending from the housing and having a distal end spaced from the fluid inlet of the housing;
  - a pressure amplifying mechanism disposed in the housing,
  - wherein the housing is couplable to a gas source and the amplifying mechanism is responsive to the gas source to convert low pressure fluid fed through the fluid inlet to a high pressure fluid output at the distal end of the cannula.
2. A fluid jet surgical cutting instrument according to claim 1, wherein the pressure amplifying mechanism pulses the fluid output.
3. A fluid jet surgical cutting instrument according to claim 2, wherein the pressure amplifying mechanism comprises a piston member which separates an interior of the housing into at least a driving chamber and a retracting chamber, the chambers being connected to the gas source to effect reciprocating movement of the

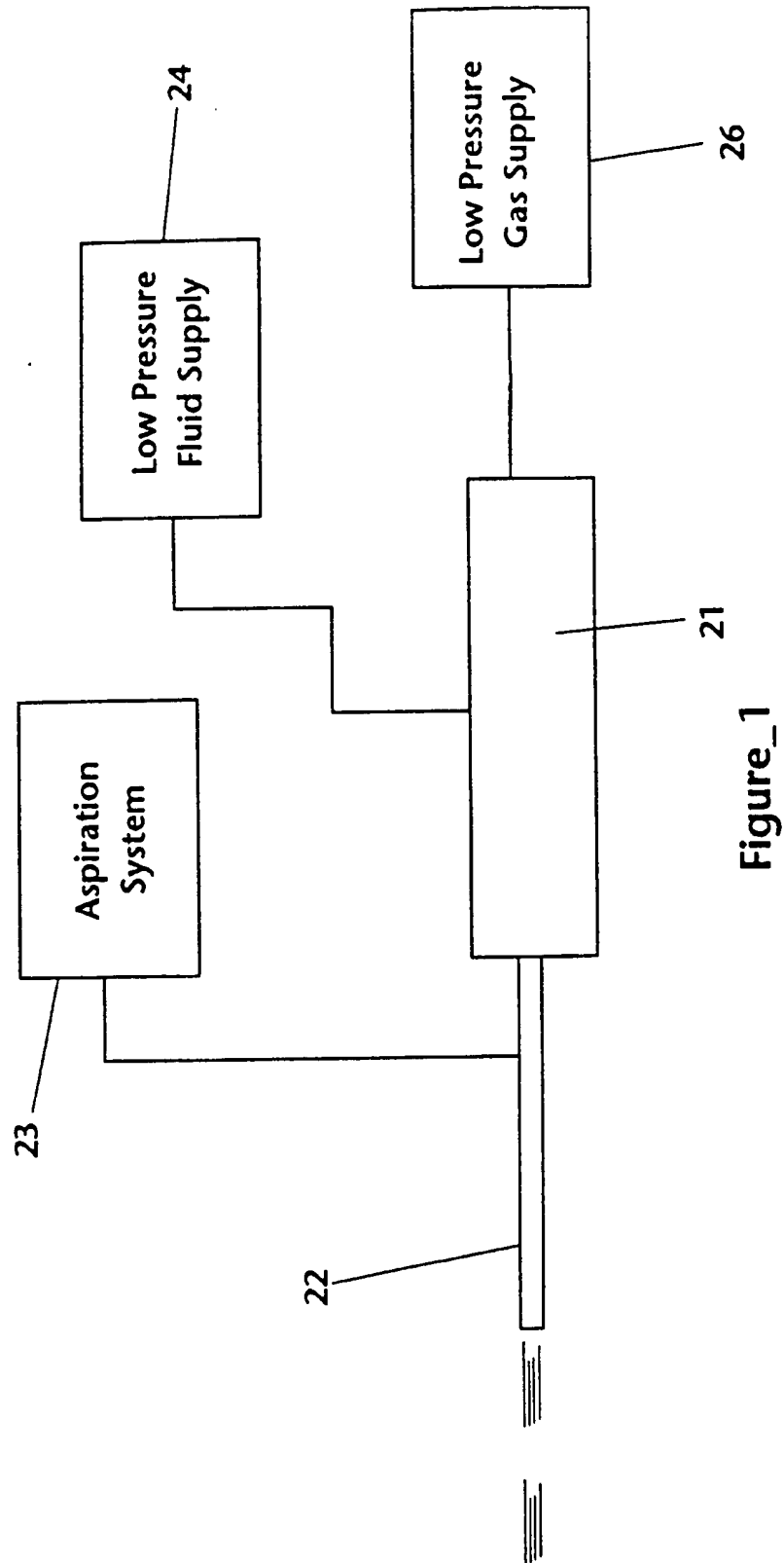
piston member to pulse the high pressure fluid output.

4. A fluid jet surgical cutting instrument according to claim 1, wherein the pressure amplifying mechanism comprises a piston separating an interior of the housing into at least a driving chamber and a fluid chamber such that a first end of the piston is adapted to be driven reciprocally by pressurized gas, and a second end of the piston is adapted to pump said low pressure fluid and form said high pressure fluid pulses, the gas source communicating with the driving chamber and the fluid source communicating with the fluid chamber, and the fluid chamber communicating with the cannula.
5. A fluid jet surgical cutting instrument according to claim 4, further comprising a pressure relief valve disposed between the fluid chamber and the cannula, the relief valve having a threshold pressure less than a maximum pressure in the driving chamber, such that when the maximum pressure exceeds the threshold pressure, the relief valve opens and fluid is expelled through the cannula under high pressure.
6. A fluid jet surgical cutting instrument according to Claim 4 or 5, wherein a retracting chamber is disposed between the driving chamber and the fluid chamber such that the piston mechanism separates the interior into a proximal portion having the driving chamber, and a distal portion having the retracting chamber and the fluid chamber.
7. The fluid jet surgical cutting instrument of claim 4, 5 or 6;
  - wherein said first end of said piston is disposed within a first bore, said first bore including first valve means for providing said pressurized gas to said driving chamber and said retracting chamber in serial, alternating fashion to drive said piston to reciprocate, wherein said valve means includes a valve pintle disposed in reciprocating piston fashion in a valve bore;
  - an inlet port extending to said driving chamber to admit pressurized gas therein, said valve pintle disposed to extend from said second end of said valve bore to selectively block and open said inlet port; and
  - actuating means for venting said retracting chamber and said first end of said valve bore to ambient pressure, whereby said pressurized gas drives said valve pintle to open said inlet port and admit pressurized gas to said driving chamber and urge said piston to translate in a

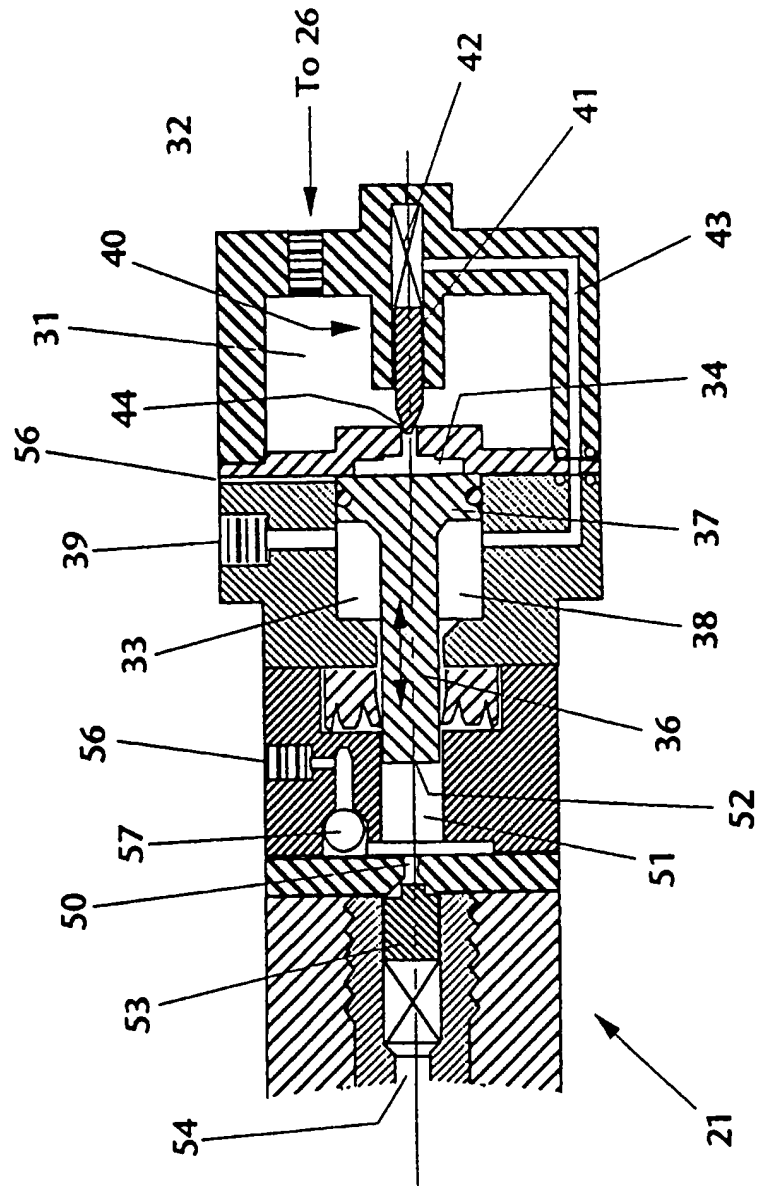
pumping stroke.

8. The fluid jet surgical cutting instrument of claim 7, further including;
  - pressure bleed means for venting said driving chamber and permitting gas pressure buildup in said retracting chamber to urge said piston to retract from said pumping stroke, said second end of said piston being disposed in a pump bore, said pump bore connected to deliver high pressure fluid pulses to said cannula;
    - a high pressure relief valve interposed between said pump bore and said cannula to admit only high pressure fluid to said cannula; and
    - check valve means for admitting said low pressure fluid to said pump bore.
9. The fluid jet surgical cutting instrument of claim 7 or 8, further including compression spring means for resiliently biasing said valve pintle toward said second end of said valve bore to close said inlet port.
10. A fluid jet surgical cutting instrument according to any one of the preceding claims, adapted to work with a gas source which is at a low pressure, such that low pressure gas and low pressure fluid are admitted to the housing to produce the high pressure fluid output from the pressure amplifying mechanism.
11. A fluid jet surgical cutting instrument according to claim 10, wherein the fluid output is at a pressure at least five times greater than fluid pressure input to the housing from the fluid source.
12. A fluid jet surgical cutting instrument according to any one of the preceding claims, wherein the fluid chamber is a rigid chamber.
13. A fluid jet surgical cutting instrument according to any one of the preceding claims, further comprising venting means for venting gas to effect reciprocation of the pressure amplifying mechanism.
14. A fluid jet surgical cutting instrument according to any one of the preceding claims, wherein the cannula is constructed and arranged so as to direct a plurality of high pressure fluid pulses toward a tissue target and to aspirate fluid and emulsified tissue from the vicinity of the tissue target;
  - and said housing includes handpiece means for supporting said cannula, said pres-

sure amplifying mechanism disposed within said handpiece means for generating said high pressure fluid pulses within said handpiece means from said low pressure fluid and said pressurized gas and delivering said high pressure fluid pulses to said cannula means for delivery to said tissue target.

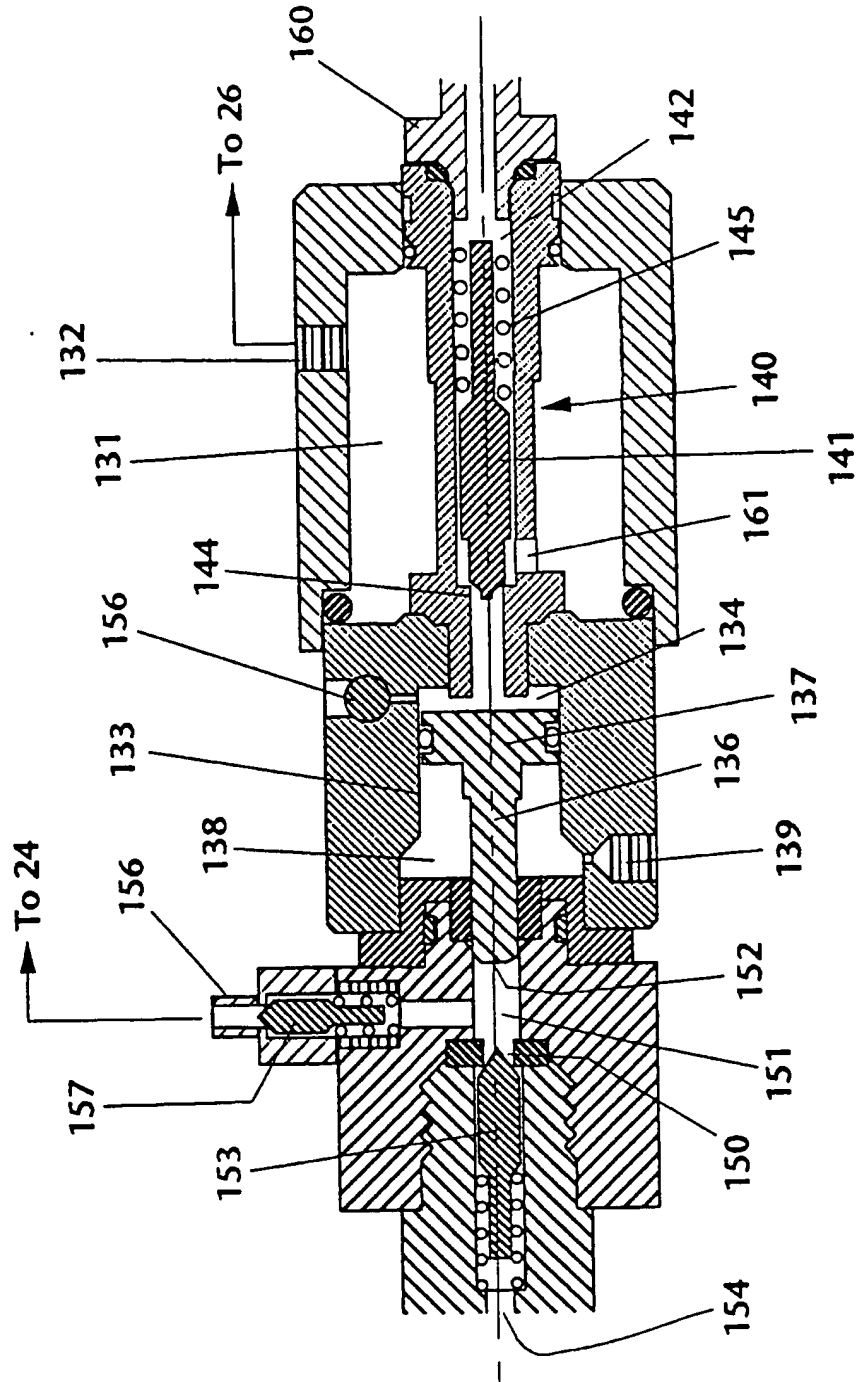


Figure\_1



**Figure\_3**





Figure\_4

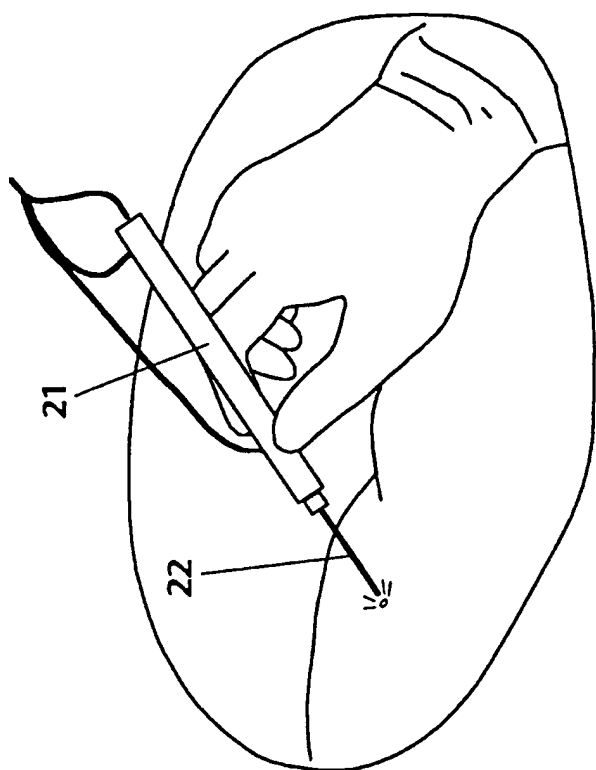


Figure 2

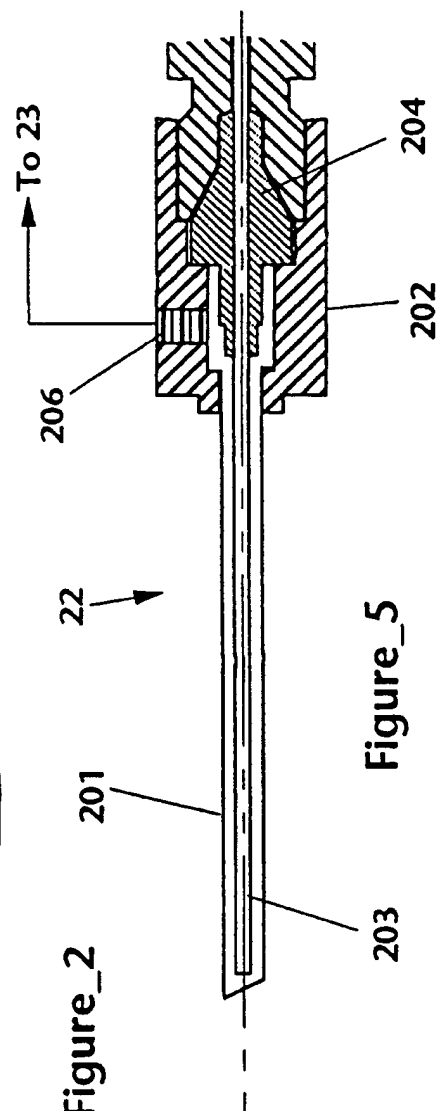


Figure 5

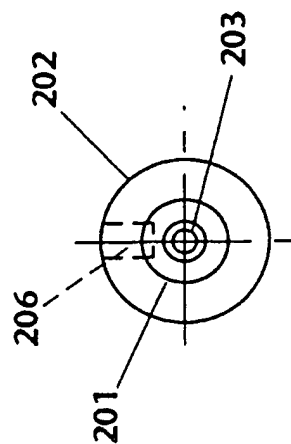


Figure 6



European Patent  
Office

# EUROPEAN SEARCH REPORT

Application Number

DOCUMENTS CONSIDERED TO BE RELEVANT			EP 94111165.0
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl. 6)
A	<u>EP - A - 0 411 170</u> (MARUI) * Abstract; fig. * --	1	A 61 B 17/32
A	<u>US - A - 5 037 431</u> (SUMMERS) * Abstract; fig. * --	1	
A	<u>US - A - 3 811 795</u> (OLSEN) * Abstract; fig. 2 * ----	1	
			TECHNICAL FIELDS SEARCHED (Int. Cl. 6)
			A 61 B F 04 B
The present search report has been drawn up for all claims			
Place of search VIENNA	Date of completion of the search 09-11-1994	Examiner NARDAI	
CATEGORY OF CITED DOCUMENTS		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons ----- & : member of the same patent family, corresponding document	
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document			